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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/011,977 | 06/15/1998 | HERMANN P.T. AMMON | 015200-054 | 1580 |

21839 7590 08/25/2004

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EXAMINER

OWENS JR, HOWARD V

ART UNIT PAPER NUMBER

1623

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/011,977

Applicant(s)

AMMON ET AL.

Examiner

Howard V Owens

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,12-16,18-22,24,25 and 27-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,12-16,18-22,24,25 and 27-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/9/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to Arguments

The following is in response to the amendment filed 3/9/04:

An action on the merits of claims 10, 12-16, 18-22, 24, 25 and 27-40 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

35 U.S.C. 112

The rejection of claims 10, 12-16, 18-22, 24, 25 and 27-40 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn.

35 U.S.C. 103

The rejection of claims 10, 12-16, 18-22, 24, 25 and 27-40 under 35 U.S.C. 103 over Ammon et al., EP 0552657 in combination with Mulshine et al., WO 95/24894 and Han, Chin. Med. Sci. J., vol. 9(1), 61-69 is maintained for the reasons of record set forth below.

The instant claims are drawn to a method of combating diseases selected from the group consisting of chronic bronchitis, glomerulonephritis, rheumatoid arthritis, cystic fibrosis, tumors and neoplasms or tumor metastases which are caused by increased leukocytic elastase or plasmin activity.

The prior art of Ammon et al. has recognized the use of Boswellic acids for the prophylaxis and or control of inflammatory processes that are caused by elevated leucotriene formation and that they inhibit the 5-lipoxygenases. Ammon et al. teach the use of Boswellic acid in the treatment of inflammatory conditions of the joints (rheumatism), bronchitis and chronic asthma (pp. 1-6). Applicant's

arguments regarding and whether the mechanism of action by Boswellic acid is dependent upon 5-lipoxygenase inhibition or the concentration of 5-lipoxygenase inhibitors is moot. The prior art has recognized the use of these compounds to treat the same conditions as applicant; therefore, there is no novelty to the invention. However, Ammon does not teach the use of Boswellic acid as an anti-tumor or anticancer agent. Mulshine et al. teaches the efficacy of 5-lipoxygenase inhibitors in the treatment of cancer, which adequately bridges the nexus between the differences in the prior art and the invention as claimed with regard to the use of Boswellic acids to treat tumors; moreover, Han further supports the usefulness of Boswellic acid derivatives in the treatment of cancer (see abstract).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use Boswellic acid or a derivative thereof to treat inflammatory processes or neoplasms.

One of skill in the art would have been motivated to use Boswellic acid or plant extracts (such as olibanum) containing Boswellic acid to treat inflammation or neoplasms as the prior art teaches the anti-inflammatory and anticancer activity associated with the use of these compounds. Applicant's connection of Boswellic acid to leukocytic elastase or plasmin activity is considered to be a discovery of one of the pathways affected by Boswellic acid and does not obviate the use of the Boswellic acid in the prior art to treat or combat inflammatory conditions, neoplasms or cancer; moreover, as the prior art has taught the efficacy of 5 lipoxygenase inhibitors in the treatment of cancer or tumors and Boswellic acid has been established in the art as a member of the class of lipoxygenase inhibitors one of skill in the art would have been provided with a reasonable expectation of success in the use of these compounds to treat cancer.

Applicant argues that the prior art had only indicated the use of 5 lipoxygenase inhibitors, such as boswellic acids for the treatment of moderate diseases, such as asthma, and not those of the present invention. However, as cited previously, Ammon et al. teach the use of Boswellic acid in the treatment of inflammatory conditions of the joints (rheumatism) and bronchitis which are the same diseases that applicant claims in claim 10.

The examiner previously argued that the chief component that is generic to all of the disease conditions cited and the progenitor of the destruction of functional tissue is inflammation. As cited by applicant in the specification, "In general, participation of human leucocytic elastase is postulated in catabolic processes of inflammations of various genesis". Thus contrary to applicant's assertions, it is clear that the target of the invention, as claimed is that of various inflammatory disease states. The examiner maintains the position that applicant's recognition of the inhibition of an enzyme does not minimize the fact that the prior art has recognized the anti-inflammatory ability of boswellic acid; moreover, since applicant has recognized that the diseases spring from an inflammatory process, applicant's arguments are not convincing enough to show that there is no reasonable expectation of success, especially when the prior art cites disease conditions of equal severity to applicant's.

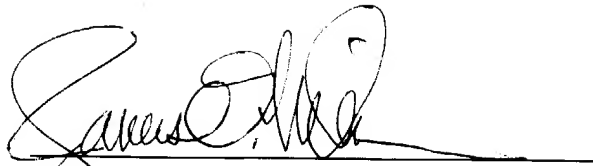
Applicant's argues against the use of the Han reference because there is no mention of human elastase nor the destruction of functional tissue. However, Han was cited to show the recognition of cancer treatment by Boswellic acid in the art. Han clearly teaches the use of Boswellic acid to treat cancer; moreover, one of skill in the art would clearly recognize that cancer is symptomatic of the destruction of functional tissue since there is uncontrolled growth and invasion of tissues with cancerous cells.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1623

Howard V. Owens
Patent Examiner
Art Unit 1623

A handwritten signature in black ink, appearing to read "James O. Wilson", written over a horizontal line.

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (571) 272-0658 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (571) 272 - 0661.